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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,280	06/20/2003	Helmut Muckter	MUCKTER-2	6448
7590	05/24/2006		EXAMINER	
Ursula B. Day Suite 4714 350 Fifth Avenue New York, NY 10118				WILLSE, DAVID H
		ART UNIT	PAPER NUMBER	3738

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/601,280	MUCKTER, HELMUT	
	Examiner Dave Willse	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 March 2006.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 4-6,8,10-15,17 and 19-25 is/are pending in the application.  
 4a) Of the above claim(s) 4-6,17,19,20 and 23 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 8,10-15,21,22,24 and 25 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

Newly submitted claims 4-6, 17, 19, 20, and 23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 4-6, 17, 19, 20, and 23, drawn to vascular connection devices disposed at a pump housing, classified in class 606, subclass 153.
- II. Claims 8, 10-15, 21, 22, 24, and 25, drawn to vascular connection devices in combination with a pump housing, impeller, motor, and webs, classified in class 604, subclass 9.

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the suture ring or vascular prosthesis, for example. The subcombination has separate utility such as in creating a bypass or cardiac assistance using other well-known blood pumps.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification and divergent required searches, restriction for examination purposes as indicated is proper.

Since the applicant has received an action on the merits for the originally presented invention, Invention II has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 4-6, 17, 19, 20, and 23 are withdrawn from consideration as being directed to a non-elected invention (37 CFR 1.142(b) and MPEP § 821.03).

The Applicant has again failed to specifically point out the support in the original disclosure for each of the added claims and claim limitations. Additionally, the Applicant does not identify which of the foreign priority applications and what particular locations in said applications provide support for the revisions to the specification. Attention is directed to MPEP §§ 714.02 and 2163.06.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to because in replacement paragraph **0029**, assigning a ratio or percentage for comparing a pair of cross sections is vague and indefinite because cross sections are associated with geometrical shapes rather than particular numerical values. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The percentages are vague and indefinite for reasons presented above. It is again recommended that a ratio (expressed as a percentage) of respective *diameters* or respective *areas* be positively recited instead. The value of “50%” (claim 12, line 2) contradicts the value of “80%” (claim 11, line 3).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 10-12, 21, 22, and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rau et al., US 6,116,862, which discloses a pump housing **10**, an impeller **22**, a motor **16**, webs **53** and **54** for firmly holding the motor within the pump housing (Figure 3; column 4, lines 9-12), and vascular connection devices taking on the form of frustoconical surfaces formed at the inlet **12** and the outlet **18** and being *capable* of directly attaching to a vascular prosthesis or to a blood vessel outside the heart for a tubeless connection, whether or not such was the intent. Regarding claim 22: column 2, line 66, through column 3, line 1; column 1, lines 37-41; etc. Regarding claim 10, the webs **53** and **54** are *capable* of housing cables for the transmission of electrical current, whether or not such was the intent; in fact, such a configuration would have been inherent because the passage **17** (column 2, lines 47-48) of the first embodiment (Figure 1) does not exist in the second embodiment (Figure 3).

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al., US 6,116,862. Vascular prostheses would have been obvious in order to replace diseased vascular tissue and/or to ensure a proper fit with inlet **12** and outlet **18**.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al., US 6,116,862, in view of Chardack, US 4,957,504. Rau et al. lack a second pump housing with an impeller and a motor. Chardack teaches two parallel pumps for effecting various types of synchronized pumping (column 5, line 54 et seq.). To similarly arrange a second blood pump in parallel with the first in the invention of Rau et al. would have been obvious in order to achieve various combinations of continuous or pulsatile flow and/or to simply provide a redundant pump as a backup, with further motivation having been provided by both references being directed to ventricular assist via rotary pumping. Regarding claim 14, an adaptable connection device would have been obvious from the harness **78** of Chardack in order to facilitate control of the two pumps (Chardack: column 5, lines 54-62). Regarding claim 15, the word “drive” means “[t]o push, propel, or press onward forcibly” (*Webster’s II New Riverside University Dictionary*, 1984); the Rau et al. motor **16** is certainly capable of accelerating and decelerating (if not reversing direction), so the motor is capable of propelling or forcing the impeller **22** in one direction or the other (via the magnets **28**) so as to speed up or slow down said impeller.

The Applicant’s remarks have been considered. The Applicant asserts that Rau et al. “clearly has no tubeless connection and in fact is not suitable for a tubeless connection” (page 9, last two lines, of the Applicant’s reply of March 15, 2006). The Applicant has not provided a definition of the term “tubeless” in a manner prescribed by MPEP § 2111.01; the claims must be given their broadest reasonable interpretation consistent with the specification (MPEP § 2111). The Applicant’s vascular connection devices encompass vascular prostheses (instant claims 23 and 24), which are virtually all *tubular* in form. The Applicant further contends, without evidence, that “if one were to attempt to make a tubeless connection with the inlet and outlet of

the pump, the vascular tissue would die off in the shortest time and the connection become leaky" (page 10, lines 18-20, of said reply). The inlet **12** and outlet **18** of Rau et al. are *capable* of connecting to vascular prostheses (many of which possess adequate mechanical properties for maintaining the viability of such connections), to blood vessel transplants, to blood vessels within cadavers (e.g., for training purposes), and to blood vessels within animals (e.g., for experimentally testing whether the Applicant's allegations are correct). Regarding claim 10, the Applicant makes reference to column 4, lines 9-25, of Lau et al., and emphasizes the statement that "[o]therwise, the blood pump of FIG. 3 is constructed the same as the blood pump of FIG. 1" (Lau et al.: column 4, lines 22-23). But this statement refers to components other than the closed, tapered projection **52** (column 4, lines 1-8; Figure 3) associated with the radial guide blades **53** and **54** as an alternative to the motor housing protruding from the end wall **14** (column 2, lines 42-48; Figure 1). The examiner sees no way of passing the electric wires into the motor housing **15** other than through the guide blades or webs **53** and **54**; if the Applicant has in mind another possibility, then the Applicant should elaborate on this for the record.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114 (MPEP § 706.07(b)). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Dave Willse  
Primary Examiner  
Art Unit 3738